

K912757

APPENDIX J

OCT 29 1997

510(K) SUMMARY
SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR
ROYAL SHIELD POWDER FREE NITRILE EXAMINATION GLOVES

Contact person : Ong Lay Mau

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Device Information:

Trade Name - ROYAL SHIELD™ POWDER FREE COLORED NITRILE EXAMINATION GLOVES

Common Name - Exam gloves

Classification Name - Patient examination glove (per 21 CFR 880.6250)

Classification Information - Class I, 80 LZA - Nitrile patient examination glove, Powder free
 Meets all requirements of the ASTM Draft Standard Specification for Nitrile Examination Gloves for Medical Application.

Device Description:

Class I Nitrile patient examination gloves 80LZA, powder free and meeting all the requirements of the ASTM Draft Standard Specification for Nitrile Examination Gloves for Medical Application.

Intended Use of Device:

A medical glove to be worn on the hand of the health care and similar personnel to prevent contamination between health care personnel and patient.

Technological Characteristics of Device:**1. Dimension**

DIMENSION	ASTM D3578-95	ROYAL SHIELD
X-Small	70 mm +/-10 mm	70 - 75 mm
Small	80 mm +/- 10mm	80 - 85 mm
Medium	90 mm +/- 10mm	90 - 97 mm
Large	100mm +/- 10mm	105 - 100 mm
Length	230 mm minimum for all sizes	240mm min. for all sizes
Thickness - Finger Palm	0.08mm minimum 0.08mm minimum	0.08 mm min. 0.08 mm min.

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2. Physical Properties

TESTS	TENSILE STRENGTH			ULTIMATE ELONGATION		
	ASTM D 3578-95	ASTM DRAFT NITRILE	SHIELD GLOVES MFR'S	ASTM D 3578-95	ASTM DRAFT NITRILE	SHIELD GLOVES MFR'S
BEFORE AGING	14.0 MPa	12.5 MPa	15.6 MPa	<u>700%</u>	<u>500%</u>	<u>650%</u>
AFTER AGING 22 HRS @ 100°C	14.0 MPa	12.5 MPa	14.5 MPa	500%	400%	575%

Our Royal Shield™ Powder free, Colored Nitrile gloves meets all the current ASTM D 3578-95 standards except for Ultimate Elongation Percentages Before Aging.

However, these gloves do meet all the specifications of the ASTM Draft Specification for "Nitrile Rubber Examination Gloves for Medical Application" (see APPENDIX B-1) and will conform to all the requirements of the final ASTM standard for Nitrile gloves when published.

3. Water Tight Test

Using the FDA specified 1,000 ml water leak test, 80 pieces of each size of the gloves were tested and our results are as given below:

BATCH #	SIZE	SAMPLE SIZE	LEAK STATUS	NUMBER LEAKED
9705261002	Small	80	No	0
9705261002	Medium	80	Yes	1
9705261002	Large	80	Yes	1

The above meets the FDA Water Leak Test Requirements.

4. Biocompatibility

The test results below shows that the gloves meet FDA biocompatibility requirements:

BIOCOMPATIBILITY TESTS
Primary Dermal Irritation Test
Skin Sensitization Study

RESULTS
Passes
Passes

5. Total Residual Powder Content & Presence of Cornstarch

TESTS	FDA INTERNAL REQUIREMENTS	SHIELD GLOVES MFR'S
RESIDUAL POWDER CONTENT (ASTM DRAFT METHOD)	NOT EXCEEDING 2 MG PER GLOVE	RANGE: 1.6-2.0 MG/ GLOVE MEAN : 1.8 MG PER GLOVE
CORNSTARCH PRESENCE (IODINE TEST)	NEGATIVE	NEGATIVE

Our above glove conforms to FDA's Internal Requirement not to exceed 2 mg/glove of total powder residue (using ASTM Draft Method for Residual Powder on Medical Gloves) and negative Iodine test.

CONCLUSION:-

It is concluded that the Royal Shield™ Powder Free, Colored Nitrile gloves meet:-

- ASTM D 3578-95 with the exception of Ultimate Elongation Percentages Before Aging (700% standard Vs. 650% for our product).
- ASTM Draft Standard Specification for Nitrile Examination Gloves for Medical Application and will conform to this final standard when published.
- FDA Internal Requirement not to exceed 2 mg/glove of total powder residue (using ASTM Draft Method for Residual Powder on Medical Gloves).
- ASTM D 5151-90 Test Method for Detection of Holes in Medical Gloves
- the FDA Water Leak Test requirements



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT 29 1997

Mr. Ong Lay Mau
Executive Director
Shield Gloves Manufacturer (M) Sdn. Bhd.
87, 2nd. Floor, Jalan SS 15/4-C
Subang Jaya
Petaling Jaya, Selangor Darul Ehsan
Malaysia

Re: K972757
Trade Name: ROYAL SHIELD™ Non-Sterile Powderfree,
Colored Nitrile Examination Glove (Blue)
Regulatory Class: I
Product Code: LZA
Dated: October 11, 1997
Received: October 20, 1997

Dear Mr. Mau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

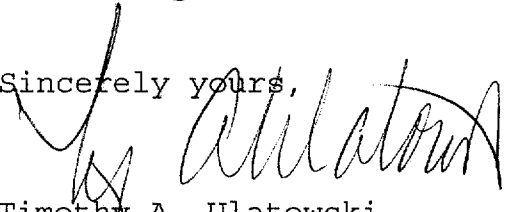
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: Shield Gloves Manufacturer (M) Sdn Bhd.

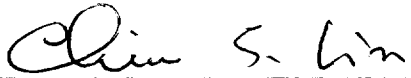
510K Number: K972757

Device Name: ROYAL SHIELD™ Powder Free Colored Nitrile Examination Gloves (Blue)

Indications For Use :

This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.

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Concurrence of CDRH Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972757

Prescription Use
Per 21 CFR 801.109

OR

Over-The-Counter.....X.....